



October 6, 2015

Donald M. Smith
6EN-AS
U.S. Environmental Protection Agency
Region 6
Compliance Assurance and Enforcement Division
1445 Ross Avenue, Suite 1200
Dallas, Texas 75202

Dear Mr. Smith:

This letter is in response to the email you sent to Mr. Steve Ortiz, the General Manager of Sterigenics Santa Teresa facility on September 24, 2015. Following are the responses to the questions regarding the ethylene oxide (EO) release at the Santa Teresa facility on September 14, 2015.

- 1. Provide the name, title, email, phone number and mailing address for the person to whom correspondence should be sent regarding the release.**

Kathleen Hoffman
Sr. Vice President – Global EH&S
2015 Spring Road, Suite 650
Oak Brook, IL 60523
630-928-1758
Khoffman@sterigenics.com

- 2. Who owns and/or operates the location where the event occurred?**

Sterigenics U.S., LLC

- 3. Briefly describe the facility, e.g. discuss what activities take place on-site and what substances are produced, processed, handled or stored on-site.**

This facility performs batch sterilization of medical products and bioburden reduction of spice products using ethylene oxide (EO). On occasion, propylene oxide (PO) is used to treat various nut products. EO is stored in 400-pound cylinders. The maximum quantity of EO at this facility is 20,000 pounds or 50 cylinders. The medical supplies and/or spices are placed in the sterilization chambers on pallets where the EO is introduced. Upon completion of the sterilization cycle, EO is removed from the sterilization chamber and routed to an emission control system, which destroys the EO. The pallets are then removed from the sterilization chambers and placed in an aeration room. The aeration room is a high-temperature with continuous air-flow environment that allows the treated product to off-gas residual EO. The emissions from the aeration room are routed to a catalytic oxidizer for destruction.

4. **What process units or equipment were involved in the event? Provide a brief description and process flow diagram for the processes involved.**

Sterilization Chamber #2 was involved in the incident. For further information, please refer to the attached process flow diagram.

5. **At the time of the incident, was the facility operating under a Title V Air Permit?**

This facility operates under state permit No. 0733-M15-R1 issued by the New Mexico Air Quality Bureau. The facility does not meet the applicability criteria for a Title V permit and thus was not issued a Title V permit by the permitting agency.

6. **What is the SIC or NAICS code for the facility where the event occurred?**

The facility's SIC code is 7389 and NAICS code is 561910.

7. **Did the event take place at a Risk Management Program covered process?**

Yes, the process is covered by the Risk Management Program.

8. **Provide a detailed description and timeline of the event. Include the best known start time and duration of the incident and the timeline for any emergency response.**

The release was caused by the Chamber #2 door hand wheels not being tightened sufficiently during the sterilization cycle. This caused the EO to escape the chamber and activated local Lower Explosive Limit (LEL) alarms. The plant was evacuated in response to the LEL alarms. After building evacuation, responding facility employees donned proper personal protective equipment (PPE) and re-entered the facility to investigate. The chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels. The release began at approximately 7:40 am and ended around 8:10 am PST. The duration of the incident was approximately 30 minutes.

9. **What specific substances were released during the event, including the estimated or known amounts of each substance? Include all air contaminants that were released during the event, even those materials with release amounts below the reportable quantity.**

We estimate that about 37 pounds of EO vapor was released inside the facility from Sterilization Chamber #2. The facility has exhaust fans that vent indoor air directly to atmosphere from the roof. In addition, Chamber #2 is located adjacent to the aeration room which has a negative pressure and draws some air from the chamber room into the aeration room. The aeration room is controlled by a catalytic oxidizer with a minimum control efficiency of 99%. We estimate approximately 10% of the EO released during this event, or about 4 pounds, vented through the aeration room and catalytic oxidizer. Therefore, the total EO released to the atmosphere would be 0.04 pounds via the catalytic oxidizer and 33 pounds to the outside environment via the exhaust fans.

- 10. Have there been any investigations or audits of the event? Are investigations or audits pending? Who performed the investigations or audits? Provide a copy of the reports, audits, or any other analysis describing the causes and consequences of the event, including all draft reports and/or draft audit results.**

Sterigenics has conducted an internal investigation into the EO release event. The internal investigation of this event included Operations, Global EH&S, Global Engineering, and SteriPro Lab. A copy of the initial EO release report is included. A more detailed investigation report with corrective actions is also being developed.

- 11. What is the initial best known cause or root cause of the event? Were there any additional contributing factors that you are aware of?**

The root cause for this EO release was the Chamber 2 door hand wheels not being tightened sufficiently during the sterilization cycle. A key contributing factor was that this sterilization cycle operated under positive-pressure conditions during the injection of EO into the chamber. Another contributing factor is that this positive pressure cycle was being operated in sterilization chambers with manual doors.

- 12. What measures have been taken to address the findings, conclusions or recommendations of the investigations or audits?**

As an immediate corrective action taken within 30 minutes of the incident occurring, the chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels. Based on our investigation, the following list of additional corrective actions and expected completion dates:

- Review incident with all facility employees and response to incident to identify any areas for improvement - Complete
- Review incident and investigation with all Sterigenics locations – October 30, 2015
- Limit the operation of this cycle to chambers with automated doors and gaskets to ensure doors are properly locked until further controls, described below, are implemented on applicable manual chambers – Complete
- Install equipment to implement chamber door hand wheel tightening notification system for manual chambers – Complete
- Implement tracking log system where two operators confirm and verify the tightening of the manual doors – Complete
- Review safety concerns with customer and see what they can do to minimize the product sterilized with the positive-pressure cycle and confirm a timeline for the elimination of this cycle – October 9, 2015
- Modify leak or emergency procedures to immediately estimate release amount for all events that trigger an LEL alarm – December 30, 2015
- Inventory all positive-pressure sterilization cycles and perform risk assessment – October 30, 2015

- Conduct EO Release emergency drills on all shifts at Santa Teresa facility – November 30, 2015

13. Are there any findings, conclusions, or recommendations that have not been addressed fully, and if so, what measures remain to be taken, and what is the expected timeline for implementing those measures?

See #12 for corrective actions and expected date of completion.

14. Were there any fatalities or injuries attributed to the event? If yes, explain.

No fatalities or injuries occurred during this event.

15. Did you, or anyone else, issue any evacuation, road closure, or shelter-in-place orders as a result of the event for your facility or surrounding community? If yes, explain.

According to Sterigenics Global EH&S procedures, the facility is required to evacuate the building upon an LEL alarm greater than 25%. A 30% LEL alarm occurred and activated the building evacuation notification system. Therefore, all facility employees evacuated. No evacuations, road closures, or shelter-in-place order were issued for the community.

16. Was there any property or equipment damage, both on-site and/or off-site, that resulted from the event? If yes, explain.

No, there was no property or equipment damage that resulted from the event.

17. What emergency response measures were taken, by you or anyone else, to stop and/or to minimize hazards from the event?

As stated above, the facility responded to the LEL alarms by evacuating the building. LEL alarms above 25% also interlock all chamber controls and put them in a cycle stop or hold status as a safety control. Accordingly, all production was immediately suspended. After facility responders donned appropriate PPE, they re-entered the facility to investigate. The chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels.

18. Did you or anyone else the facility perform any air monitoring during or after the event, including any routine monitoring? If so, then please provide a summary of the results.

The Chamber #2 area is continuously monitored by strategically placed LEL detectors which alarm at 10% of the LEL (3,000ppm) or higher. There is also a Gas Chromatograph area monitor port in the vicinity which detects low level concentration of EO for worker protection. During the event, LEL alarms greater than 25% activated a facility evacuation.

19. Identify and provide copies of any industry standards, internal standards, SOPs, or manufacturer's recommendations related to the incident including equipment, process units, and personnel activities involved in the incident.

Sterigenics has a number of standard operating procedures for the operation of its sterilization equipment and its environmental, health and safety procedures. In addition, the facility and its process equipment is built to applicable industry standards. One specific internal standard applicable to this EO release event is the Emergency Operating Procedure for High level EO Alarms (EOP-050). Attached is a copy of this procedure.

20. Please provide any documents associated with the identification of hazards at your facility related to the incident.

Sterigenics has a number of risk assessment tools that are used to identify hazards associated with our process and operations. We have an EHS procedure "Hazard Identification – Risk Assessment" (EHS-201) that outlines all such risk assessments. Attached is a copy of this procedure. One critical risk assessment is the Process Hazard Analysis (PHA) for the EO process at the Santa Teresa facility. This is completed and updated within our Process Safety Management and Risk Management Program. To better understand the specific hazards associated with ethylene oxide, also attached is the ethylene oxide Safety Data Sheet.

21. Has any local, state, or federal agency conducted an investigation or requested information regarding the event? If so, please provide the name and contact information for each agency person who conducted an inspection or requested information.

Per emergency notification requirements in 40 CFR 302.6 and 40 CFR 355.40, upon discovering the potential release was likely greater than the 10-pound reportable quantity and in accordance with notification requirements in 40 CFR §302.6 and 40 CFR §355.40, facility personnel immediately notified the following agencies of the release:

- National Response Center (NRC) (Case # 1128845)
- Dona Ana County/Las Cruces LEPC, and
- New Mexico State Emergency Response Commission (SERC)

In addition, we submitted a follow up letter in accordance with 40 CFR §355.40 to Mr. David Almaguer of the Dona Ana County/Las Cruces LEPC and Ms. Susan Walker and Mr. Henry Jolly of the NM SERC. We have not received notice of any investigation that has been conducted. A copy of the follow up letter is attached for your reference.

If you have any questions regarding this letter or our investigation please contact Kathy Hoffman (see contact information in #1) or me at 630-928-1771 or kwagner@sterigenics.com

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Wagner". The signature is fluid and cursive, with the first name "Kevin" and last name "Wagner" clearly distinguishable.

Kevin Wagner
Director, EH&S

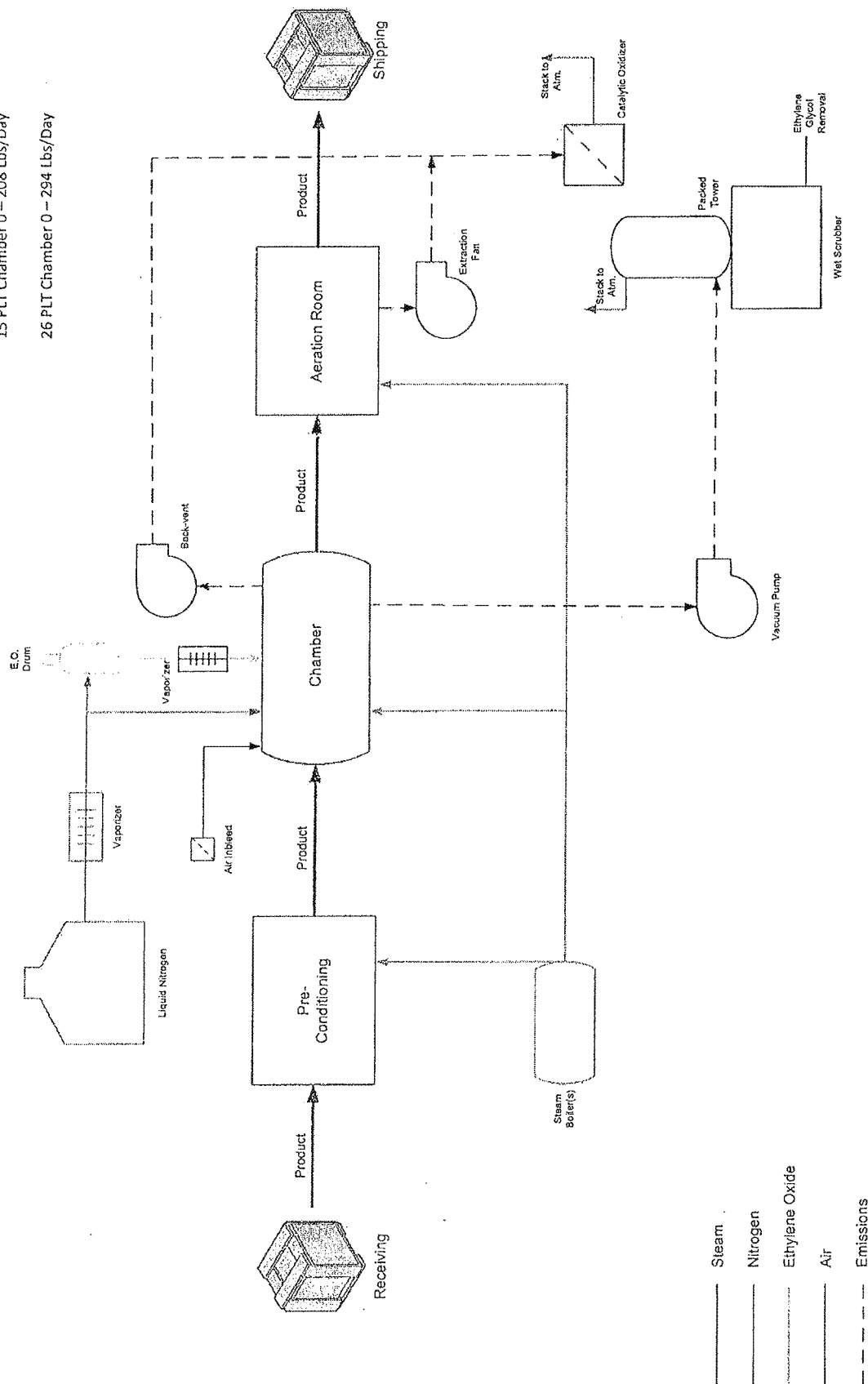
cc: Steve Ortiz – General Manager
Juan Segovia – Vice President Operations
Kathy Hoffman – Sr. Vice President – EH&S

Encl.

Attachment 1: Process Flow Diagram

Sterigenics Process Flow Diagram

13 PLT Chambers 0 – 126 Lbs/Day
 30 PLT Chambers 0 – 371 Lbs/Day
 15 PLT Chamber 0 – 208 Lbs/Day
 26 PLT Chamber 0 – 294 Lbs/Day



Attachment 2: Initial EO Release Report



SPILL AND RELEASE INVESTIGATION REPORT

NOTE: COMPLETE THIS FORM WHENEVER THERE IS A SPILL OR RELEASE OF A HAZARDOUS SUBSTANCE INCLUDING ETHYLENE OXIDE

A. Facility Originating Report

Facility: Santa Teresa	Phone: 575-589-9300
Address: 2400 Airport Rd	City/State/Prov.: Santa Teresa, NM 88008

B. Incident Description

1. Date/Time

Start Date: 14-Sep-2015	End Date: 14-Sept-2015	
Start Time: 7:42 am	End Time: 8:08 am	Total Time: 00:26 min

2. Environmental Conditions (check all that apply)

Location of Spill/Release: Chamber 1 and 2 vault	
Spill/Release onto or into: <input checked="" type="checkbox"/> Air <input type="checkbox"/> Ground <input type="checkbox"/> Water	Release Occurred: <input checked="" type="checkbox"/> Indoors <input type="checkbox"/> Outdoors
Weather type: <input type="checkbox"/> Overcast <input checked="" type="checkbox"/> Sunny <input type="checkbox"/> Precipitation	Wind Direction and Speed: SSE at 8.1 mph


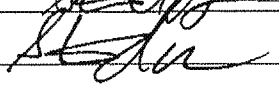
3. Substance Description:

Name of Substance Spilled/Released: Ethylene Oxide	
Amount(s) Spilled/Released: Undetermined	Amount Recovered: TBD
Extremely Hazardous Substance? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Reportable Quantity of Substance: 10 lbs
Source Container: Sterilization Chamber 2	Capacity of Container: 13 Pallet Chamber
Brief Description of Incident: During processing in Ch.2, in Gas Inject A, the door hand wheels on rear door were not tightened sufficiently. This caused EtO to escape the Chamber into Chamber Module Room and activated a 30% LEL alarm.	
Corrective Actions Taken: Plant evacuated and Facility Employees first responders donned PPE and re-entered the facility and tightened door wheels to mitigate the leak.	

C. Notifications

Entity Notified	Phone No.	Time/Date of notification	Person notified
Corporate EHS	630-928-1700	Approx: 8am 14 Sep 15	Juan Segovia
National Resp Center	800-424-8802	3:45 pm 18 Sep 2015	Operator on Duty
Office of Emerg/Mgmt	575-647-7900	3:48pm 18 Sep 2015	David Almaguer
NM Emergency Response Comm	505-476-0617	3:50pm 18 Sep 2015	Henry Jolly/ Left Voicemail

D. Review and Approval

	Print Name	Signature	Date
Spill Report Prepared by	Stephen Ortiz		21 Sep 15
Facility (General) Manager	Stephen Ortiz		21 Sep 15

Attachment 3: Emergency Operating Procedure for High EO Level Alarms
(EOP-050)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Attachment 4: Risk Assessment Procedure

EHS-201

(b) (4)

(b) (4)



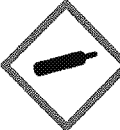

(b) (4)

Attachment 5: Safety Data Sheet for Ethylene Oxide (EO)

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER	
1.1. GHS product identifier.	Ethylene Oxide
Other means of identification.	Oxirane
1.2. Recommended use and restrictions on use.	Recommended: Chemical intermediate for production of anti-freeze, polyester resins, non-ionic surfactants and specialty solvents; sterilizing agent for controlling microorganisms in health care applications; fumigant for controlling insect infestation in whole and ground spices and cosmetics; sterilization of musical wind instruments. Advised Against: Consumer use.
1.3. Supplier's details.	Name: ARC Specialty Products c/o Balchem Corporation Address: 52 Sunrise Park Road New Hampton, NY 10958 USA Phone number: +1 845-326-5611 Fax number: +1 845-326-5706 Internet: www.arcspecialtyproducts.com Email: sds@balchem.com
1.4. Emergency phone number.	<p>EMERGENCY TELEPHONE (24 hrs. / 7 days per week)</p> <p>In Canada: CANUTEC (613) 996-6666 In US: CHEMTREC (800) 424-9300 Outside US & Canada: CHEMTREC (703) 527-3887</p>

2. HAZARDS IDENTIFICATION	
2.1. GHS classification of the substance or mixture and any national or regional information.	Flammable Gas 1 Pressurized Gas (Liquefied Gas) Carcinogen Category 1B Mutagen Category 1B Acute Toxicity Category 3 (Inhalation); Category 4 (oral) Eye Irritant Category 2A Specific Target Organ Toxicity – Single Exposure 3 Skin Irritant 2
2.2. GHS label elements, including precautionary statements.	Product Label Name: ETHYLENE OXIDE Signal Word: DANGER <div style="text-align: center;">     </div> <p>Hazard statement:</p> <p>H220: Extremely flammable gas. H280: Contains gas under pressure; may explode if heated H302: Harmful if swallowed H315: Causes skin irritation H319: Causes serious eye irritation H331: Toxic if inhaled H335: May cause respiratory irritation</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>H340: May cause genetic defects</p> <p>H350: May cause cancer</p> <p>Precautionary statement:</p> <p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.</p> <p>P261: Avoid breathing gas/vapours.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P280: Wear protective gloves/protective clothing/ eye protection/face protection.</p> <p>P281: Use personal protective equipment as required.</p> <p>P301;P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P330: Rinse mouth.</p> <p>P302;P352: IF ON SKIN: Wash with plenty of soap and water.</p> <p>P362: Take off contaminated clothing and wash before reuse.</p> <p>P332;P313: If skin irritation occurs: Get medical advice/attention.</p> <p>P304;P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305;P351;P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337;P313: If eye irritation persists: Get medical advice/attention.</p> <p>P312: Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P308;P313: IF exposed or concerned: Get medical advice/attention.</p> <p>P321: Specific treatment: See first aid section of SDS.</p> <p>P377: Leaking gas fire: Do not extinguish, unless leak can be stopped safely.</p> <p>P381: Eliminate all ignition sources if safe to do so.</p>
--	--

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	P403;P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P410;P403: Protect from sunlight. Store in a well-ventilated place. P501: Dispose of contents/container in accordance with local/regional/national/international regulation.
2.3. Other hazards which do not result in classification or are not covered by the GHS.	EUH006: Explosive with or without contact with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance:

Chemical identity.	Ethylene Oxide
Common name, synonyms, etc.	Oxirane, EO, EtO, Dihydroxirene, 1-2 Epoxyethane, Dimethylene Oxide, Oxane, Oxirane, Alpha/Beta-Oxidoethane, Oxacyclopropane
CAS number, EC number, etc.	CAS#: 75-21-8; EC#: 200-849-9 (from EINECS) Chemical Family: Epoxide Formula: (CH ₂) ₂ O Molecular Weight: 44.053 g/mol
Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.	Contains no other components or impurities which will influence the classification of the product.

3.2. Mixture:

The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cutoff levels.	Chemical Identity:	Concentration:	CAS No.:
	No applicable information found (i.e. material is not a mixture).		

4. FIRST AID MEASURES

4.1. Description of first aid measures.	<p>EYE CONTACT: Immediately flush eyes, including the entire surface of the eyes and under the eyelids, gently but thoroughly with plenty of running water for at least 15 minutes. Obtain medical attention immediately. NOTE: Never wear contact lenses when working with ethylene oxide.</p> <p>SKIN CONTACT: Immediately flush skin thoroughly with water for at least 15 minutes while removing contaminated clothing and shoes. Obtain medical attention immediately. Treat for possible cryogenic injury, if needed by warming affected areas with tepid water (wrap with a blanket if lukewarm water is not available). Wash clothing before reuse and discard contaminated leather articles such as shoes and belts.</p>
---	--

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
	<p><u>INHALATION:</u> Remove exposed person to fresh air. If breathing has stopped, give artificial respiration then have qualified personnel administer oxygen, if needed. Get immediate medical attention.</p> <p><u>INGESTION:</u> If patient is conscious give plenty of water (minimum of two glasses) but DO NOT INDUCE VOMITING. This material is corrosive. Keep head lower than hips to avoid aspiration, should vomiting occur. Get medical attention immediately.</p> <p><u>MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:</u> Preexisting skin, eye and respiratory disorders; lung, blood, nervous system and peripheral nerve disorders.</p>		
4.2. Most important symptoms/effects.	<p><u>SIGNS AND SYMPTOMS OF OVEREXPOSURE:</u> Effects include skin, eye and respiratory tract irritation or burns. Central nervous system effects initially cause headache, dizziness and nausea and in extreme cases, unconsciousness and death. Peripheral nerve damage may result in muscular weakness, giddiness, irrational behavior and loss of sensation in the extremities. Dulling of the sense of smell may occur.</p>		
4.3. Indication of immediate medical attention and special treatment needed, if necessary.	<p><u>NOTE TO PHYSICIANS:</u> Respiratory symptoms include nausea, vomiting and irritation of the nose and throat. Pulmonary edema may occur. Respiratory effects may be delayed. Consider oxygen administration. If a chemical burn is present, decontaminate skin and treat as any thermal burn. No specific antidote is known, however consider gastric lavage and administration of a charcoal slurry.</p>		
5. FIREFIGHTING MEASURES			
5.1. Suitable (and unsuitable) extinguishing media.	<p><u>EXTINGUISHING MEDIA:</u> Carbon dioxide, dry chemical or water spray for small fires. Water spray, polymer or alcohol resistant foams for large fires. Dilution of liquid ethylene oxide with 22 volumes of water should render it non-flammable. Dilution with 100 parts water to one part of ethylene oxide vapor may be required to control build up of flammable vapors in closed systems. Water spray can be used to reduce flame intensity, cool fire-exposed containers and dilute spills to render non-flammable.</p>		
5.2. Specific hazards arising from the chemical.	<p><u>EMERGENCY OVERVIEW:</u> Colorless liquid or heavier-than-air gas with a sweet, ether-like odor. Extremely flammable liquefied gas which burns in the absence of oxygen and can explode when exposed to elevated temperatures. Toxic when inhaled. Causes severe skin and eye irritation or burns and respiratory tract irritation; effects may be delayed. Harmful if swallowed or absorbed through the skin. Contact with liquid may cause frostbite.</p>		

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p><u>Statement of Hazards:</u> DANGER! Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly Reactive. Harmful or fatal if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.</p> <p>HAZARD RATINGS: (0 = minimum; 4 = maximum)</p> <p><u>HMIS Rating:</u> Health = 3 Flammability = 4 Reactivity = 3 Personal Protection Code = X (Consult your supervisor or standard operating procedures for special handling directions.)</p> <p><u>NFPA Rating:</u> Health = 3 Flammability = 4 Reactivity = 3</p> <p><u>UNUSUAL FIRE AND EXPLOSION HAZARDS:</u> Ethylene oxide is dangerously explosive under fire conditions; it is flammable over an extremely large range of concentrations in air and burns in the absence of oxygen. Liquid ethylene oxide is lighter than water (floats) and vapors are heavier than air and may travel along ground long distances to sources of ignition, and then flash back. Avoid storage at warm temperatures [around 100 °F (38 °C)] in order to prevent polymerization. Do not store at temperatures above 125 °F (52 °C) under any circumstances. Containers are fitted with metallic plugs which melt and release contents when temperature increases to a range of 157-170 °F (69-77 °C). Vapors are extremely flammable and are readily ignited by static charge, sparks and flames at concentrations above 2.6%.</p>
--	--

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

5.3. Special protective equipment and precautions for firefighters.	<p>SPECIAL FIRE-FIGHTING PROCEDURES: Wear NIOSH-approved self-contained breathing apparatus (SCBA) operated in the pressure-demand mode and full chemical-resistant protective clothing. Evacuate all personnel from danger area and keep upwind. Immediately cool containers with water spray from maximum safe distance. Stop flow of gas, if without risk, while continuously cooling containers with water. Do not extinguish flames unless flow is stopped, since explosive re-ignition can occur. Remove containers from fire area, if without risk. Refer to the most current edition of the "North American Emergency Response Guidebook" for isolation and evacuation distances.</p>
---	--

6. ACCIDENTAL RELEASE MEASURES	
6.1. Personal precautions, protective equipment and emergency procedures.	<p>PRECAUTIONS: Treat any ethylene oxide leak as an emergency. All cleanup personnel must wear full protective equipment. Evacuate all personnel from the area except those directly engaged in stopping the leak or in cleaning up.</p>
6.2. Environmental precautions.	<p>ENVIRONMENTAL: Dike runoff water, if possible, to prevent contaminated water from entering sewers, ditches, streams and ponds. It is mandatory to call the National Response Center (800-424-8802) if 10 pounds (4.54 kg) or more is spilled or released to the environment.</p>
6.3. Methods and materials for containment and cleaning up.	<p>SPILL CLEANUP: Eliminate all ignition sources if this can be done safely. Ethylene oxide/air mixtures ignite readily and may detonate. Use water fog or spray to disperse vapors. Flood spill with water spray to dilute and render non-flammable.</p>

7. HANDLING AND STORAGE	
7.1. Precautions for safe handling.	<p>HANDLING AND STORAGE PRECAUTIONS: Wear all recommended protective clothing and devices when handling this material. Have established handling and emergency response procedures in place prior to use. Ground and bond shipping container, transfer line, and receiving container. Protect containers from physical damage and regularly inspect them for cracks, leaks or faulty valves.</p>
7.2. Conditions for safe storage, including any incompatibilities.	<p>STORAGE SEGREGATION: Store ethylene oxide in a cool, dry, well-ventilated area away from incompatible chemicals and sources of ignition. Store cylinders and drums upright; secure containers tightly; do not drag or slide; and move in a carefully supervised manner with a suitable hand truck. DO NOT STORE IN DIRECT SUNLIGHT.</p> <p>SHIPPING AND STORAGE CONTAINERS: (See 49 CFR 173.323) Ethylene oxide is shipped and stored in UN 1A1 specification drums and DOT specification drums and cylinders. Nitrogen must be charged into the container after filling with ethylene oxide, bringing the</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>total container pressure up to 50 psig. Before returning container to supplier, pressurize container with nitrogen to 50 psig total pressure; close valves and replace valve plugs tightly in outlets. Check container valves and plugs for leaks prior to shipment. In addition, please refer to the most current edition of NFPA Publication 55, 'Compressed Gases and Cryogenic Fluids Code.'</p> <p>INCOMPATIBILITIES: Ethylene oxide is very reactive. Runaway exothermic polymerization reactions can result from contamination with amines, ammonia, water, acids, bases, metal chlorides, metal oxides, metallic potassium, mercaptans, alcohols, oxidizers and many other organic and inorganic materials.</p>
--	--

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters.	Exposure Limits			
	<u>SOURCE</u>	<u>TWA (8-hr)</u>	<u>STEL (15-min)</u>	<u>OTHER</u>
	OSHA	1 ppm	5 ppm (9 mg/m ³)	0.5 ppm action level (8-hr TWA)
8.2. Appropriate engineering controls.	ACGIH	1 ppm (1.8 mg/m ³)	No applicable information found	800 ppm IDLH
	<p>ENGINEERING CONTROLS: Ethylene oxide, a major fire hazard, can burn in the absence of oxygen. All electrical devices used in areas processing or handling ethylene oxide must be engineered and designed to the applicable local electrical/fire codes. Safeguards can include designing electrical devices as explosion-proof and/or intrinsically safe. When considering engineering controls, users of ethylene oxide should consult the current edition of NFPA 55 (Compressed Gases and Cryogenic Fluids Code, Section 14: Storage, Handling and Use of Ethylene Oxide for Sterilization and Fumigation). Sterilization facilities should consult NIOSH Publication NO. 2007-164 (Alert: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities).</p> <p>VENTILATION: Install and operate general and local exhaust ventilation systems powerful enough to maintain airborne levels of ethylene oxide below the OSHA PEL in the worker's breathing area. Ventilation systems must be of maximum explosion-proof design. Emission controls must be in compliance with Federal, State and local regulations.</p> <p>SAFETY SHOWERS: Have eyewash stations, emergency deluge showers, and washing facilities available in all work areas.</p>			

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>OTHER PROTECTION: Design all engineering systems to be explosion-proof in any area where this gas may be present. Container and system must be electrically grounded/bonded before unloading. Practice good personal hygiene; always wash thoroughly after using this material. Do not eat, drink or smoke in work area.</p>
8.3. Individual protection measures, such as personal protective equipment.	<p>RESPIRATORY PROTECTION: Refer to OSHA respirator regulations cited at 29 CFR 1910.134 and 29 CFR 1910.1047. Wear a NIOSH-approved full facepiece respirator for routine use situations where atmosphere is at or above OSHA's Action Level. Do not exceed the maximum use conditions of the respirator. For emergency or non-routine uses where concentrations are unknown, wear an SCBA with a full facepiece operated in the pressure-demand or positive pressure mode.</p> <p>EYE PROTECTION: Always wear chemical safety glasses. If splashing may occur, wear a full face shield as a supplementary protective measure over safety glasses. NEVER WEAR CONTACT LENSES when working with ethylene oxide.</p> <p>SKIN PROTECTION: Wear impervious gloves (see www.ethyleneoxide.com for permeation data); boots; aprons; head cover; and clean impervious body-covering clothing to prevent any possibility of skin contact. Launder contaminated clothing and discard contaminated leather shoes, belts, etc.</p>

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties.

Appearance (physical state, color, etc.).	Colorless liquid or gas
Odor.	Sweet ether-like
Odor threshold.	261 ppm – detectable 500 to 700 ppm - recognizable
pH.	7, neutral (100 g/L in water)
Melting point/freezing point.	-169 °F (-112 °C)
Initial boiling point and boiling range.	50.7 °F (10.4 °C)
Flash point.	Tag Closed Cup: < 0 °F (< 18 °C)
Evaporation rate.	100% volatile by volume
Flammability (solid, gas).	Flammable
Upper/lower flammability or explosive limits.	Upper flammable limit: 100% vol/vol Lower flammable limit: 2.6% vol/vol
Vapor pressure.	1095 mmHg @ 20 °C
Vapor density.	1.5 (Air = 1)
Relative density.	0.875 at 20 °C
Solubility (ies).	100% in water
Partition coefficient: n-octanol/water.	-0.3
Autoignition temperature.	833 °F (445 °C); Burns in the absence of air
Decomposition temperature.	~932 °F (~773 °K)
Viscosity.	0.255 centipoise at 80 °F
Oxidizing properties.	Not an oxidizer

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

10. STABILITY AND REACTIVITY

10.1. Reactivity.	Not reactive under normal conditions. Under abnormal conditions (for example external heating, contamination), thermal decomposition and runaway polymerization can occur and may lead to explosion.
10.2. Chemical stability.	STABILITY: Material is stable for extended periods in closed, airtight, pressurized containers at room temperature, under normal storage and handling conditions. Vapors may explode when exposed to common ignition sources. In the presence of catalysts, polymerization and decomposition of liquid may occur and is accelerated at temperatures above 800 °F (426 °C).
10.3. Possibility of hazardous reactions.	HAZARDOUS POLYMERIZATION: Dangerous exothermic polymerization reaction can occur when ethylene oxide is contaminated or when heated.
10.4. Conditions to avoid (e.g., static discharge, shock or vibration).	CONDITIONS TO AVOID: Avoid storage at warm temperatures [around 100 °F (38 °C)] in order to prevent polymerization. Do not store at temperatures above 125 °F (52 °C) under any circumstances. Avoid contact of ethylene oxide with incompatible chemicals to avoid highly exothermic polymerization reaction. Prevent exposure to all sources of ignition such as heat, flame, lighted tobacco products or electrical or mechanical sparks.
10.5. Incompatible materials.	See section 7.2
10.6. Hazardous decomposition products.	HAZARDOUS DECOMPOSITION PRODUCTS: Ethylene oxide undergoes thermal decomposition to form carbon dioxide and carbon monoxide gases.

11. TOXICOLOGICAL INFORMATION

11.1. Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);	PRIMARY ROUTES OF EXPOSURE: Inhalation; eye contact; skin contact/absorption.
11.2. Symptoms related to the physical, chemical and toxicological characteristics;	<p>ACUTE HEALTH EFFECTS:</p> <p>INHALATION: Inhaling concentrated vapor may cause serious health effects, possibly death. Inhalation may progressively cause mucous membrane and respiratory irritation, headache, vomiting, cyanosis, drowsiness, weakness, loss of coordination, CNS depression, lachrymation, nasal discharge and salivation, gasping, and labored breathing. Delayed effects may include nausea, diarrhea, edema of the lungs, paralysis, convulsions and possibly death. NOTE: Ethylene oxide has a high odor threshold (> 250 ppm) and the sense of smell does not provide adequate protection against its toxic effects.</p> <p>EYE CONTACT: Liquid ethylene oxide is severely irritating and corrosive to the eyes and contact can cause swelling of the conjunctiva and irreversible corneal injury. Contact with liquid ethylene oxide can cause frostbite.</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
	<p>Vapors may cause eye irritation, tearing, redness and swelling of the conjunctiva.</p> <p>SKIN CONTACT: Prolonged contact with liquid ethylene oxide can cause a local erythema, edema, and formation of blisters. Response is more severe on damp skin. There may be a latency period of several hours prior to the onset of symptoms. Ethylene oxide may be absorbed by the skin, and sustained contact may produce adverse effects such as headache, dizziness, nausea and vomiting. Ethylene oxide is a skin sensitizer and some individuals may suffer an allergic skin reaction. Skin contact may also cause allergic contact dermatitis in some exposed individuals. Liquid ethylene oxide evaporates rapidly and may chill the skin causing frostbite.</p> <p>INGESTION: This relatively unlikely route of exposure is expected to cause severe irritation and burns of the mouth and throat, abdominal pain, nausea, vomiting, collapse and coma. Aspiration may occur during swallowing or vomiting, resulting in lung damage.</p>		
11.3. Delayed and immediate effects and also chronic effects from short- and long-term exposure;	<p>CHRONIC HEALTH EFFECTS:</p> <p>SKIN CONTACT: Long term effects are unknown but are expected to be similar to acute effects of skin exposure.</p> <p>EYE CONTACT: Some cases of cataract formation have been reported.</p> <p>INHALATION: Respiratory irritation which can result in permanent lung injury, chromosomal aberrations and peripheral neurotoxic effects with a numbing of the sense of smell. Cognitive and CNS impairment may result from long term exposures.</p> <p>INGESTION: May cause anemia, gastrointestinal irritation, effects on liver, kidneys, and adrenal glands.</p> <p>CARCINOGENICITY: OSHA classifies ethylene oxide as a cancer/reproductive hazard and considers that, at excessive levels, ethylene oxide may present reproductive, mutagenic, genotoxic, neurologic and skin sensitization hazards. ACGIH classifies ethylene oxide as "A2" - suspected human carcinogen. NTP classifies ethylene oxide as a known human carcinogen. IARC classifies ethylene oxide in Group I (carcinogenic to humans). NIOSH classifies ethylene oxide as a potential human carcinogen.</p>		

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

<p>11.4. Numerical measures of toxicity (such as acute toxicity estimates).</p>	<p><u>TOXICOLOGICAL - ACUTE INHALATION:</u> LC₅₀ (1 hr. exposure) 5748 ppm (male rat) 4439 ppm (female rat) 5029 ppm (rat - combined sexes) Various mammalian species exposed to lethal concentrations of ethylene oxide had symptoms of mucous membrane irritation, central nervous system depression, lacrimation, nasal discharge, salivation, nausea, vomiting, diarrhea, respiratory irritation, loss of coordination and convulsions.</p> <p><u>TOXICOLOGICAL - CHRONIC INHALATION:</u> Symptoms of chronic exposure are similar to those observed in acute studies, including lung, kidney and liver damage and testicular tubule degeneration in some species. Studies demonstrated neuromuscular effects as the most sensitive indicator of ethylene oxide overexposure.</p> <p><u>TOXICOLOGICAL - ACUTE DERMAL:</u> No dermal LD₅₀ information is available on this product. It is expected to be corrosive to rabbit skin.</p> <p><u>TOXICOLOGICAL - CHRONIC DERMAL:</u> No chronic dermal toxicity data are available on this product.</p> <p><u>TOXICOLOGICAL - EYE:</u> No eye irritation animal data are available on this product; however, it is expected to be extremely irritating to rabbit eyes.</p> <p><u>TOXICOLOGICAL - ACUTE INGESTION:</u> The acute oral LD₅₀ for this product is: 330 mg/kg, rat.</p> <p><u>TOXICOLOGICAL - CHRONIC INGESTION:</u> The effects of chronic ingestion of this product are unknown.</p> <p><u>CARCINOGENICITY:</u> A recent assessment of available epidemiology studies related to ethylene oxide concluded that the evidence indicates that ethylene oxide does not cause heart disease, an excess of cancers overall, or brain, stomach or pancreatic cancers which were seen in some animal and isolated human studies. The findings with respect to leukemia and non-Hodgkin's lymphoma are less definitive. While the majority of the evidence does not indicate that ethylene oxide causes these cancers, there are some suggestive trends. A longer follow-up of ethylene oxide was completed in 2004 to better clarify these relationships. NIOSH reported no overall elevated risk for any type of cancer or other diseases as compared to the general population, however, among those workers with very high ethylene oxide exposure (combination of exposure level and years worked); there was evidence of an elevated risk for blood</p>
---	---

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>cancers among men and breast cancer among women. Two inhalation studies with rats demonstrated carcinogenic responses consisting of increased incidences of mononuclear cell leukemia, peritoneal mesotheliomas, and primary brain tumors. In 2-year inhalation studies with mice there was evidence of carcinogenic activity as indicated by dose-related incidences of benign or malignant neoplasms of the uterus, mammary gland, and hematopoietic system (lymphoma).</p> <p>MUTAGENICITY: While ethylene oxide has demonstrated, in epidemiological studies with exposed workers, an increased incidence of chromosomal aberrations and sister chromatid exchanges, the relevance of such effects to human health hazard evaluation is currently uncertain. In rodent studies, dose related exposure to ethylene oxide induces increases in numbers of adducts in DNA and hemoglobin. Laboratory studies with mice have shown that acute exposure to ethylene oxide at 300 ppm and above caused testicular injury as evidenced by concentration-related increased embryonic deaths following mating of exposed males to non-exposed females (Dominant-Lethal Test).</p> <p>NEUROTOXICITY: Effects are similar to those of acute (short term) exposure, namely, headaches, nausea, diarrhea, lethargy and irrational behavior. Muscle weakness, loss of sensation in the extremities and a reduction in the sense of smell and/or taste may also result. Studies on workers indicate that CNS and cognitive impairment may result from chronic exposures to ethylene oxide.</p> <p>REPRODUCTIVE EFFECTS: Some limited epidemiological data suggests that women exposed to ethylene oxide have a greater incidence of miscarriage. A one-generation reproduction study in rats showed decreased numbers of pups at 100 ppm but not at 33 ppm. In a two-generation reproduction study involving exposure of rats to ethylene oxide vapor for 6 hrs/day, 5 days/week, there was parental toxicity at 33 ppm and 100 ppm. Post implantation losses with reduction in litter size and offspring body weight were found at 33 ppm and 100 ppm. The no-observable effect concentration for adult toxicity, offspring effect and reproductive effect was 10 ppm.</p> <p>TERATOLOGY: Inhalation development toxicity studies with rats exposed to ethylene oxide vapor at concentrations of 50 ppm, 125 ppm and 225 ppm showed that maternal toxicity occurred at 125 and 225 ppm. Fetotoxicity, evidenced by reduced fetal body weight, occurred at all concentrations. At 225 ppm and</p>
--	---

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>to a lesser extent at 125 ppm an increased incidence of skeletal variants was found. There was no evidence of embryotoxicity or malformations.</p> <p>TARGET ORGANS: Overexposure to this product may affect the skin, eyes, respiratory system, liver, kidneys, brain, blood, reproductive system and central nervous system.</p>
--	--

12. ECOLOGICAL INFORMATION

12.1. Ecotoxicity (aquatic and terrestrial, where available).	<p>AQUATIC TOXICITY: Acute 96-hr. LC₅₀ data: 57-84 mg/L, fathead minnow (<i>Pimephales promelas</i>) 90 mg/L, goldfish (<i>Carassius auratus</i>) 137-300 mg/L, water flea (<i>Daphnia magna</i>) Material is slightly toxic to marine invertebrates. 48 hr. LC₅₀ in brine shrimp: 490 mg/L</p>
12.2. Persistence and degradability.	<p>CHEMICAL FATE INFORMATION: BOD₅: 0.35 p/p. BOD₁₀: 1.1 p/p. BOD₂₀: 1.3 p/p.</p>
12.3. Bioaccumulative potential.	<p>Log octanol/water partition coefficient (log K_{ow}) is low. Partitioning from water to oil is low. Bioconcentration is not expected to occur due to high water solubility and a low log K_{ow}. Ethylene oxide hydrolyzes to ethylene glycol. Biodegradation of ethylene oxide occurs at a moderate rate after acclimation (3-20% degradation after 5 days; 70% after 20 days). Biodegradation is expected in a wastewater treatment plant. Ethylene oxide has an estimated half life in the atmosphere of 105 days. EO does not readily absorb into sediments or soils and does not persist in soils; if absorbed, soil organisms will over time convert EO to glycols eliminating any persistence in the soil.</p>
12.4. Mobility in soil.	EO does not readily absorb into sediments or soils.
12.5. Results of PBT and vPvB	No applicable information found.
12.6. Other adverse effects.	No applicable information found.

13. DISPOSAL CONSIDERATIONS

13.1. Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.	<p>WASTE MANAGEMENT/DISPOSAL: When disposed, ethylene oxide is a RCRA hazardous waste with waste code U115 (Commercial chemical product - listed for toxicity and ignitability). Waste ethylene oxide may be incinerated in an approved hazardous waste incinerator or can be biologically treated in an approved facility. DO NOT INCINERATE ANY ETHYLENE OXIDE CONTAINERS. Ethylene oxide is banned from land disposal. Dispose of waste materials in accordance with all applicable Federal, State and local laws and regulations.</p>
---	---

14. TRANSPORT INFORMATION

14.1. UN number.	UN 1040
14.2. UN proper shipping name.	Ethylene Oxide

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
14.3. Transport hazard class (es).	<p><u>DOT</u> Primary: 2.3 (Poison Gas); Secondary: 2.1 (Flammable Gas) Poison-Inhalation Hazard Zone D Reportable Quantity 10 lb (4.54 kg)</p> <p><u>IMO</u> Primary: 2.3 (Toxic Gas); Secondary: 2.1 (Flammable Gas)</p> <p><u>TDG (from or within Canada)</u> Primary: 2.3 (Toxic Gas); Secondary: 2.1 (Flammable Gas)</p> <p>Shipments of residual amounts of ethylene oxide are considered hazardous material. All facilities shipping or receiving ethylene oxide are subject to registration as a shipper of hazardous material (49 CFR 107, Subpart G). All facilities handling ethylene oxide must also maintain a written security plan (49 CFR 172.00 – 804, 49 CFR 172.704)</p>		
14.4. Packing group, if applicable.	Not applicable		
14.5. Marine pollutant (Yes/No).	No		
14.6. Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.	See Section 7.2		
14.7. Transportation in bulk according to Annex II of MARPOL 73/78 and the IBC Code.	Product is not supplied in bulk		

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations specific for the product in question.		
US Federal:	CERCLA:	Section 103: Reportable Quantity – 10 lb (40 CFR 302.4)
	CWA:	Release into a waterway may require reporting to the National Response Center @ 800-424-8802 (40 CFR 116.4).
	FIFRA	<p>If this chemical is a pesticide product registered by the United States Environmental Protection Agency, it is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.</p> <p><u>EPA Registration No. 36736-2 and EPA Registration No. 36736-8</u> DANGER! Causes eye and skin burns. Harmful if inhaled. May cause nervous system damage. Cancer hazard and reproductive hazard. May be fatal if inhaled in high concentrations. May cause irritation of the respiratory tract. May cause immediate or delayed skin irritation or blisters. May cause allergic skin reaction. Do not breathe vapor. Highly flammable liquid and gas under pressure.</p>
	RCRA:	If discarded in purchased form, this product is a listed and characteristic hazardous waste. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal whether a material containing the product or derived from the product should be classified

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

		as a hazardous waste (40 CFR 261.20-24).
	RMP:	Listed under the EPA Chemical Accidental Prevention Provisions (Risk Management Plan: 40 CFR 68.130) as a Toxic with a 10000 lb Threshold Quantity
	SARA TITLE III:	Section 302 Extremely Hazardous Substances – Listed; 1000 lb Threshold Planning Quantity (40 CFR 355 Appendix A) Section 304 – Listed 10 lb Reportable Quantity (40 CFR 302.4) Section 311/312 Hazard Categories – Acute, Chronic, Fire, Reactive, Sudden Release (40 CFR 370.66) Section 313 Toxic Chemicals – Listed (40 CFR 372.65)
	TSCA:	On TSCA inventory.
	Other EPA	EPA list of Hazardous Air Contaminants: Listed EPA Organic Hazardous Air Pollutant (HAP) list (40 CFR 61.01): Listed EPA list of Pesticide Chemicals (40 CFR 180.151): Listed EPA NESHAPS (40 CFR 63.360) VOC Rule: 100% VOC
	FDA/USDA:	Not applicable.
	OSHA:	This product is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. Ethylene Oxide Standard 29 CFR 1910.1047
	Other OSHA:	Listed under the Process Safety Management standard (29 CFR 1910.119) with 5000 lb Threshold Quantity.
US State:		California Proposition 65: Listed; cancer hazard; reproductive hazard California Director's List: Listed Florida Hazardous Substance List: Listed Massachusetts Extraordinarily Hazardous Substance List: Listed Minnesota Hazardous Substance List: Listed New Jersey Hazardous Substance List: Listed sn 0882 (Special Hazardous Substance; Environmental Hazardous Substance) Pennsylvania Right-to-know List: Listed
Canadian:	DSL:	Listed as Oxirane (published 5 April 1994)
	WHMIS:	Ingredient Disclosure List: Listed 0.1%, item 725 (1310) Classification: A; B1; D1A; D2A; D2B; F This MSDS complies with the Canadian Controlled Product Regulations.
EU:	CLP:	This product is not sold into the European Union.
	EINECS:	
	REACH:	
	Safety Data Sheets:	

16. OTHER INFORMATION INCLUDING INFORMATION ON PREPARATION AND REVISION

Last Revision Date:	See top of each page under 'Effective Date'	
Reason for Issue:	Rev A supersedes Rev. 22 Jul 2009	Reformatted per OSHA GHS. Added part 10.1. Changed 11.4 Acute Ingestion LD50 from 72 to 330 mg/kg (no evidence located to support 72; web review, including IPCS. 2003. Ethylene Oxide. Geneva, World Health Organization, International Program on Chemical Safety, Concise International Chemical Assessment Document 54, p 1-57. http://www.inchem.org/documents/cicads/cicads/cicad54.htm .
Risk Phrases Used:	See Section 2.	
Hazard Ratings:	See Section 5.2	

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

THE FOLLOWING ABBREVIATIONS MAY BE USED IN THIS DOCUMENT:

ACGIH	American Council of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
BOD 5, 10, 20	Biochemical Oxygen Demand, 5, 10 or 20 day
CAS	Chemical Abstract Service
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CLP	Classification, Labeling and Packaging
CNS	Central nervous system
CWA	Clean Water Act
D.O.T. or DOT	Department of Transportation
DSL	Domestic Substance List (Canada)
EC ₅₀	Effective concentration which induces a response halfway between the baseline and maximum.
EC	European Community
ECL	Existing Chemicals List (Korea)
EINECS	European Inventory of Existing Commercial Substances
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GHS	Globally Harmonized System
HAP	Hazardous Air Pollutant
HMIS	Hazardous Materials Information System
IARC	International Agency for Research on Cancer
IBC	International Bulk Chemical Code
IDL	Ingredient disclosure list
IDLH	Immediately Dangerous to Life and Health
IMO	International Maritime Organization
K _{St}	Deflagration Index
LC ₅₀	Median lethal concentration for 50% mortality of subject species by the inhalation route
LD ₅₀	Median lethal dose for 50% mortality of subject species by the oral or dermal route
LD _{Lo}	Median lethal dose low; the lowest dose of a substance introduced by any route other than inhalation reported to have caused death in humans or animals.
LEL / LFL	Lower Explosive Limit / Lower Flammable Limit
MARPOL	International Convention for the Prevention of Pollution from Ships
MSHA	Mine Safety Health Administration
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NFPA	National Fire Protection Association
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PBT	Persistent Bioaccumulative Toxic
PEL	Permissible Exposure Limit (default 8 hour day, 40 hour week TWA)
p/p	Parts per part
Ppm	Parts per million
p.s.i.g. or psig	Pounds per square inch (gauge pressure)
PSM	Process Safety Management
PVC	Polyvinyl chloride
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Substances
REL	Recommended Exposure Limit (default 10 hour day, 40 hour week TWA)
RMP	Risk Management Plan

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

SARA	Superfund Amendment and Reauthorization Act of 1990
SCBA	Self-contained breathing apparatus
STEL	Short Term Exposure Limit (default 15 minute TWA)
TD _{Lo}	Lowest dose to which humans or animals have been exposed and reported to produce a toxic effect other than cancer
TDG	Transportation of Dangerous Goods
TLV	Threshold limit value
TSCA	Toxic Substance Control Act
TWA	Time Weighted Average
UFL	Upper Flammable Limit
USDA	United States Department of Agriculture
VOC	Volatile organic chemical
vPvB	Very Persistent, Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System Regulations

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Attachment 6: Follow-up Letter to SERC and LEPC



September 25, 2015

Department of Homeland Security and Emergency Management
Attn: Susan Walker, Bureau Chief
13 Bataan Blvd.
Santa Fe, NM 87504

Dona Ana County/Las Cruces LEPC, NM
Attn: Mr. David Almaguer, EM
1170 North Solano, Ste O
Las Cruces, NM 88005

RE: Follow up Notification of Reportable Release at Sterigenic's Santa Teresa, NM Facility

To whom it may concern:

The purpose of this letter is to provide required follow-up notification information regarding a reportable release of ethylene oxide (EO) which occurred at our facility located at 2400 Airport Road in Santa Teresa, New Mexico. The release occurred on September 14, 2015; however, at that time we did not believe the release could be greater than the reportable quantity of 10 pounds based on alarm conditions. After further investigation into the facility alarms and process information, we determined on Friday, September 18, 2015, that the release could have been greater than 10 pounds. Upon discovering this potential release was likely greater than the 10-pound reportable quantity and in accordance with notification requirements in 40 CFR §302.6 and 40 CFR §355.40, facility personnel immediately notified the following agencies of the release:

- National Response Center (NRC) (Case # 1128845)
- Dona Ana County/Las Cruces LEPC, and
- New Mexico State Emergency Response Commission (SERC)

Following is the requested immediate information for the release in accordance with 40 CFR §355.40(a):

- 1) **Chemical name or identity of any substance involved in the release:** The chemical substance released was gaseous ethylene oxide (CAS #75-21-8).
- 2) **Indication of whether the substance is an extremely hazardous substance (EHS):** Ethylene oxide (EO) is listed as an extremely hazardous substance.
- 3) **Estimate of the quantity released into the environment:** An estimated 33 pounds of EO was released into the environment.
- 4) **The time and duration of the release:** The release began at approximately 7:40 am and ended at 8:10 am on September 14, 2015. The total duration of the release was approximately 30 minutes.

Sterigenics US LLC
2015 Spring Road, Suite 650 · Oakbrook, IL 60523
Tel 800-472-4508 · Fax 630-928-1701 · www.sterig

- 5) **The medium or media into which the release occurred:** We estimate that about 37 pounds of EO vapor was released inside the facility from sterilization Chamber 2. The facility has exhaust fans that vent indoor air directly to atmosphere from the roof. In addition, Chamber 2 is located adjacent to the aeration room which has a negative pressure and draws some air from the chamber room into the aeration room. The aeration room is controlled by a catalytic oxidizer with a minimum control efficiency of 99%. We estimate approximately 10% of the EO released during this event, or about 4 pounds, vented through the aeration room and catalytic oxidizer. Therefore, the company estimates that the total EO released to the atmosphere would be 0.04 pounds via the catalytic oxidizer and 33 pounds to the outside environment via the exhaust fans.
- 6) **Any known or anticipated acute or chronic health risks associated with the emergency and, where appropriate, advice regarding medical attention necessary for exposed individuals:** Acute exposure to EO can result in irritation of the eyes, nose, and lungs and delayed effects may include nausea and headaches. EO chronic health risks include cancer and reproductive harm. Sterigenics has EO measurement devices and alarms in the chamber room to protect its employees. During this release, Sterigenics employees were evacuated from the area when the EO concentration levels were elevated so no employees were exposed to high EO concentrations. Because of the time of the release and the release point elevation levels, there are also no anticipated adverse health impacts to the general public as a result of this release. The company received no information suggesting that anyone was impacted outside of the facility.
- 7) **Proper precautions to take as a result of the release, including evacuation:** As mentioned above, the Santa Teresa facility was evacuated as a precaution during this release event. No other special precautions are suggested.
- 8) **The names and telephone number of the person or persons to be contacted for further information:** Further information on this release can be obtained from Kathleen Hoffman, Sr. VP of Global EH&S, at 630-928-1758 or khoffman@sterigenics.com.

Following is the information requested for the written follow-up notification in accordance with 40 CFR §355.40 (b):

- 1) **Actions taken to respond to and contain the release:** The release was caused by the Chamber 2 door hand wheels not being tightened sufficiently prior to the sterilization cycle. The cycle was started and the cycle passed the negative-pressure leak check at the start of the cycle. This particular cycle, however, operates under both vacuum and slight positive pressures. During the positive-pressure portion of the cycle a slight leak developed between the gasket and the door. This caused EO to leak around the door seal. The EO activated the local Lower Explosive Limit (LEL) alarms and the plant was evacuated. After building evacuation, responding facility employees donned proper personal protective equipment (PPE) and re-entered the facility to investigate. The chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels.
- 2) **Any known or anticipated acute or chronic health risks associated with the release:** No known or anticipated acute or chronic health risks are associated with this EO release.

Sterigenics US LLC
2015 Spring Road, Suite 650 · Oakbrook, IL 60523
Tel 800-472-4508 · Fax 630-928-1701 · www.sterigenics.com

- 3) **Where appropriate, advice regarding medical attention necessary for exposed individuals.** Since no one was injured or exposed during the release (without appropriate PPE), there was no need for medical attention.

We are in the process of completing the investigation for this EO release and will implement the necessary corrective actions to prevent it from happening again. If you need further information concerning this incident or report, please contact me at 630-928-1758 or khoffman@sterigenics.com.

Sincerely,



Kathleen Hoffman
Sr. Vice President – Global EH&S

Cc: Steve Ortiz – Santa Teresa General Manager.
Henry Jolly – NMDHSEM, Hazmat Coordinator